doi: 10.47493/abantmedj.2020.18

Abant Tıp Dergisi

Araştırma Makalesi / Cilt 9 Sayı 3 Yıl 2020

Abant Medical Journal

Research Article / Volume 9 Issue 3 Year

İç Anadolu'da Üçüncü Basamak Bir Merkezde Nabız Oksimetresi Tarama Sonuçları

Pulse Oximetry Screening Results at a tertiary care center in Central-Anatolia, Turkey

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Öz

AMAÇ: Hastanemizdeki yenidoğanlarda kritik konjenital kalp defektlerinin erken tanısı için nabız oksimetresi taramasının sonuçlarını değerlendirmek ve ülke çapında bir tarama programı uygulanmadan önce sonuçlarımızı paylaşmak.
YÖNTEMLER: Bu, Nisan 2018 ile Ocak 2020 arasında 2261 bebek üzerinde yapılan retrospektif bir çalışmadır. Predüktal ölçüm için sağ taraf, duktal sonrası ölçüm için sağ veya sol ayak Nellcor nabız oksimetresi (Covidien, MA, ABD) kullanılarak ölçüldü.
BULGULAR: 2261 yenidoğanda 2261 bebeğin ortalama doğum haftası 38.05 ± 1.32 hafta ve doğum kilosu 3204.21 ± 478.28 g idi. Ortalama tarama süresi 25.9 ± 7.3 saat idi (medyan 25 saat; min – maks 7-96 saat). İlk ölçümde testi geçen bebeklerin preduktal ve postduktal satürasyon ölçümlerinin ortalama değerleri 96.46 ± 1.65 ve 95.99 ± 1.49 idi. Çalışmaya alınan bebeklerin 2247'si (% 99,38) taramadan geçti, 14'ü (% 0,61) geçemedi. Kritik konjenital kalp defektlerinde genel test yanlış pozitif oranı % 0.6 idi. Taramayı geçemeyenlerin hiçbirinde kritik konjenital kalp defekti görülmedi. Kritik konjenital kalp defektleri vakası saptanmadığından duyarlılık ve pozitif prediktif değer hesaplanamadı. Nabız oksimetre testinin özgüllüğü ve negatif prediktif değeri sırasıyla% 99.3 ve% 100 idi.
SONUÇ: Nabız oksimetreli taramanın özellikle ikinci basamak sağlık hizmeti sunan perifer bölgelerde yaygınlaştırılması gerektiğinin altını çiziyoruz. Kritik konjenital kalp defektlerinin nabız oksimetresi ile taranmasının ülkemizdeki ulusal tarama programına dahil edilmesi gerektiğine inanıyoruz.

Anahtar Kelimeler: Nabız oksimetri taraması, Konjenital kalp defektleri, Türkiye

Abstract

PURPOSE: To evaluate the results of the pulse oximeter screening for the early diagnosis of critical congenital heart defects in newborns in our hospital and to share our results before the implementation of a nationwide screening program.
METHODS: This was a retrospective study of 2261 infants evaluated between April 2018 and January 2020. Right-hand was used for preductal measurements whileright or left foot were used for post-ductal measurements and data were collected using Nellcor pulse-oximetry (Covidien, MA, USA).
RESULTS: The average birth week of infants was 38.05 ±1.32 weeks and average birth weight was 3204.21±478.28 grams. The mean screening time was 25.9 ± 7.3 hours (median 25 hours; min-max 7–96 hours). The mean values of the pre-ductal and post-ductal measurements of the infants who passed the test at the first measurement were 96.46 ± 1.65 95.99 ± 1.49. Two thousand two hundred forty-seven (99.38%) of the infants included in the study underwent screening, 14 (0.61%) could not pass. Overall, false positive rate was 0.6 % for critical congenital heart defects. Critical congenital heart defects were not seen in any of those who could not pass the scan. Sensitivity and positive predictive value could not be calculated, as no critical congenital heart defects case was detected. The specificity and negative predictive value of the pulse-oximetry test were 99.3% and 100.0 % respectively.
CONCLUSION: We highlight that screening with pulse oximetry should be popularized particularly in peripheral regions providing secondary health care services. We think that screening of critical congenital heart defects with pulse-oximetry should be included in the national screening program in our country.

Keywords: Pulse-oximetry screening, Critical congenital heart defects, Turkey

INTRODUCTION

Congenital heart defects are the most common group of congenital anomalies in newborns, with a frequency of 7- 8 in 1000 live births, approximately 30.0 % being critical congenital heart defects (1-3). Major critical congenital heart defects are; tricuspid atresia, pulmonary

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Geliş Tarihi / Received: 03.07.2020 **Çıkar Çatışması / Conflictof Interest:** Yok / None

atresia, Fallot tetralogy, truncus arteriosus, transposition of the great vessels, total anomalous pulmonary venous return, and hypoplastic left heart syndrome. Critical congenital heart diseases require an invasive procedure with a catheter or surgery in the first month of life (4). Today, in advancedcenters, most patients with congenital heart defects are diagnosed with prenatal ultrasonography and have a chance to confirm their diagnosis by fetal echocardiography. However, 30.0 % of newborns with congenital heart disease are discharged from the hospital with undiagnosed critical congenital heart defects, more often in centers that do not have these facilities (5,6). Critical congenital heart defects may be overlooked in the routine clinical examination of newborns since symptoms and signs may be subtleor no symptoms have appeared yet (7). For this reason, the American Academy of Pediatrics recommends the screening of the newborns with pulse-oximetry for the early diagnosis of critical congenital heart defects (8). Early diagnosis and treatment management are possible with this screening made for pre and post-ductal saturation, which is non-invasive and easily applicable. The high sensitivity and specificity of pulse oximetry screening have been demonstrated and confirmed by studies and meta-analysis involving many infants from different countries (9-11). Numerous countries (USA, China, Sweden, Germany) have already implemented this scanning procedure (12). Pulse-oximetry screening in our country is not yet included in the screening program of the Ministry of Health. However, many centers conduct this scanning. This study aims to evaluate the results of the pulse oximeter screening for the early diagnosis of critical congenital heart defects in newborns in our hospital and to share our results before the implementation of a nationwide screening program.

MATERIAL AND METHODS

Study design

Between April 2018 and January 2020, a total of 5558 infants were born at Necmettin Erbakan University Meram Medical Faculty Hospital.

This is a retrospective study and the screening results of 2261 babies are included. These are the babies with gestational ages over 34 weeks and were not admitted to the neonatal intensive care unit. Seven of these babies had severe congenital heart diseases diagnosed during prenatal period (hypoplastic left heart in two, total pulmonary venous return anomaly in one, transposition of the great arteries in one, tetralogy of fallot in two, and tricuspid atresia in one case). Premature babies, babies without family consent and those diagnosed with prenatal heart disease were excluded from the study. Before screening, parents were informed and their consents were obtained.

Ethics Committee approval for this study was obtained from Necmettin Erbakan University with the Ethics Committee decision number of 2020/2333.

Measurements

Before the measurement, all newborn infants underwent detailed cardiac and systemic examinations. If there were murmurs, cyanosis, and arrhythmia on physical examinations, these patients were considered symptomatic. According to the results of laboratory, imaging, and physical examination, these symptomatic patients underwent echocardiography by the pediatric cardiologist. The pulse-oximetry screening was performed by following the screening protocol proposed by the American Academy of Pediatrics (8). Infants born with spontaneous vaginal delivery were screened in the first 24 hours just before discharge. Infants born by cesarean section were screened within the first 48 hours. Right-hand was used for preductal measurement and right or left foot were used for post-ductal measurement byusing Nellcor pulse-oximetry (Covidien, MA, USA) with a disposable probe. Measurements were

conducted by a trained resident. Any screening saturation ≥ 95.0 % and saturation difference between the right hand and foot of ≤ 3.0 % was defined as passed (Measurement result is negative). If the saturation was < 90.0 % in the right hand or any foot, it was defined as failed (Measurement result is positive). If the right hand or any standing saturation was between 90.0 % and 94.0 %, or the saturation difference was at least 4.0 %, the measurement was repeated two more times with an interval of an hour. It was considered "positive" if it failed. The patients whose first measurements were negative or only one of the three measurements were positive were accepted as negative and the test was terminated. All infants with positive measurement results have echocardiography performed within 24 hours. All echocardiographic measurements were performed by a single pediatric cardiologist with 10 years of pediatric cardiology experience using the GE, Vivid T8, China device. Patients who underwent echocardiography (with cardiac symptoms and / or positive saturation measurement result) were divided into 2 groups as critical congenital heart diseases (+) and critical congenital heart diseases (-) according to the criteria previously defined in the literature (2, 13).

Statistical analysis

Data entry, statistical analysis, and reporting procedures were performed on an electronic medium. Descriptive analysis was performed for demographic and clinical characteristics of the patients. The distribution of data was assessed by using a one-sample Kolmogorov-Smirnov test. Data are demonstrated as mean ± standard deviation for normally distributed continuous variables and frequencies (percentile) for categorical variables. Values between different groups were compared using the independent-samples t-test. Mann-Whitney U test was used if the data were not normally distributed. The $\chi 2$ test was used to assess the differences between categorical variables. Test results with $p<0.05$ were considered statistically significant. Sensitivity, specificity, as well as positive and negative predictive values were calculated for pulse-oximetry screening.

Results

Between the dates we recorded, a total of 5558 live births took place in our center. We recorded the screening results of 2268 infants. Seven infants with prenatal diagnosed critical congenital heart defects were excluded from the study (Figure-1). The average birth week of infants was 38.05±1.32 and average birth weight was 3204.21±478.28 grams. Two hundred forty-eight (10.9 %) of the infants were late preterm. Rate of vaginal births were 12.0 % (n=272) and the rate for cesarean section was 88.0 % (n=1989). The mean screening time was 25.9±7.3 hours (median 25 hours; min-max 7–96 hours). The mean values of the pre-ductal and post-ductal measurements of the infants who passed the test at the first evaluation were 96.46±1.65 and 95.99±1.49. There was no difference between demographic and clinical variables between infants who passed and failed except for the birth weight (Table-1). Mothers of the infants screened most commonly had gestational diabetes at a rate of 6.1 %, followed by preeclampsia at a rate of 3.7%. There were repeat measurements for 239 infants (10.5 %). Two thousand two hundred forty-seven (99.38 %) of the infants included in the study underwent screening, 14 (0.61 %) could not pass. Overall test false positive rate was 0.6 % for critical congenital heart defects. Critical congenital heart defects were not seen in any of those who could not pass the scan (Table-2). Echocardiography was performed in 55 infants. The indications were presence of clinical finding (n = 50), test positivity (n = 14), or both (n = 9). The echocardiography results were as follows; normal variants in 47 (85.4 %), non- critical congenital heart defects in 8 (14.5 %), and critical congenital heart defects in 0 (0.0 %). Sensitivity

and positive predictive value could not be calculated, as no critical congenital heart defects case was detected. The specificity and negative predictive value of the pulse-oximetry test were 99.3% and 100.0 % respectively. The infants who passed the test were followed-up in an outpatient setting for 6 months. Among these patients, none were then diagnosed with critical congenital heart defects.

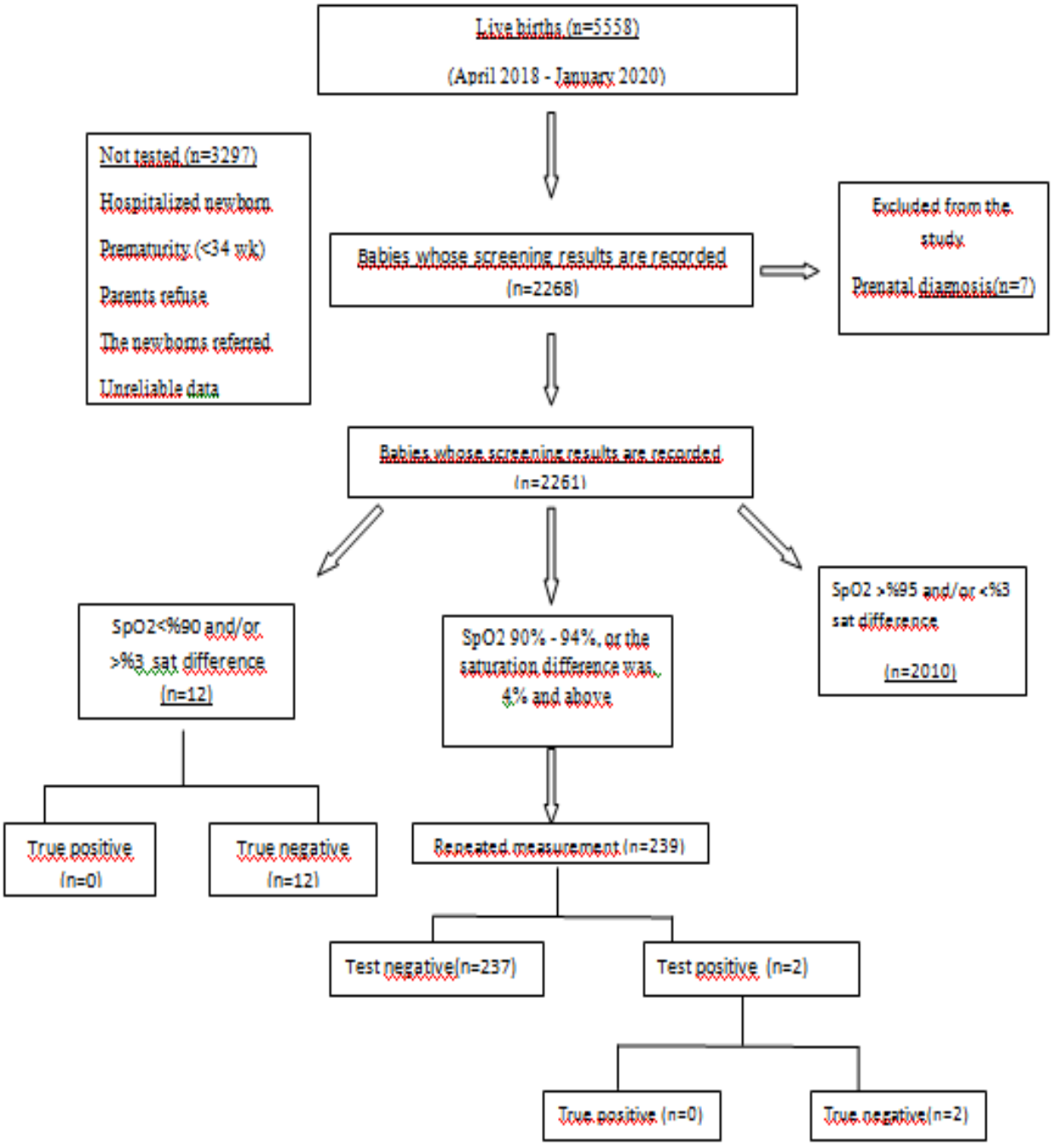

Figure 1. Seven infants with prenatal diagnosed critical congenital heart defects were excluded from the study

Tablo 1. Comparison of Demographic and Clinical Features of the Group Failing and Passing the Pulse-oximetry Screening

Variables	Groups	n	Median	Minimum	Maximum Z	Z Statistics	P value
Gestational age (w)	**Failed scan**	14	38.00	35.00	40.00	-0.108	0.914
	Passed scan	2027	38.00	33.00	42.20		
Mother Age(y)	**Failed scan**	14	27.00	24.00	43.00	-0.257	0.797
	Passed scan	2247	28.00	3.00	51.00		
Birth weight (g)	**Failed scan**	14	3745.00	2500.00	4630.00	-2.599	**0.009***
	Passed scan	2247	3200.00	1470.00	5020.00		
Height (cm)	**Failed scan**	14	50.20	45.00	55.00	-0.907	0.364
	Passed scan	2242	50.00	21.00	58.00		
Head circumference (cm)	**Failed scan**	14	34.75	32.00	38.00	-1.108	0.268
	Passed scan	2241	34.50	28.00	54.00		
1-min Apgar	**Failed scan**	14	7.00	6.00	8.00	-1.018	0.309
	Passed scan	2247	7.00	0.00	9.00		
5-min Apgar	**Failed scan**	14	8.00	7.00	9.00	-0.683	0.495
	Passed scan	2247	8.00	0.00	10.00		
Preductal Saturation SpO2	**Failed scan**	14	91.00	86.00	96.00	-6.101	0.001*
	Passed scan	2247	96.00	90.00	100.00		
Postductal Saturation SpO2	**Failed scan**	14	95.00	92.00	96.00	-3.386	0.001*
	Passed scan	2247	95.00	90.00	100.00		
Screening time (hour)	**Failed scan**	14	26.00	16.00	55.00	-1.110	0.267
	Passed scan	2247	25.00	7.00	96.00		

* Refers to situations where p <0.05.

Tablo 2. Echocardiography Results of 14 Newborns Failed from Pulse-oximetry Screening

Patient number	Sex	Gestational age (w)	Birth weight (g)	Physical Examination Finding	ECHO Results
1	Male	39	3790	No	ASD*
2	Female	37	3910	Murmur	ASD*+VSD**
3	Female	38	3320	No	ASD*
4	Female	40	4220	No	ASD*
5	Female	38	3320	No	ASD*
6	Male	39	3800	No	ASD*
7	Male	40	4630	Murmur	NORMAL
8	Male	35	2620	No	NORMAL
9	Male	38	3640	No	ASD*
10	Female	40	3700	Cyanosis	NORMAL
11	Male	40	2500	Murmur	VSD**
12	Male	35	3980	No	NORMAL
13	Female	36	2560	No	NORMAL
14	Female	38	4240,	No	NORMAL

* Atrial septal defect

** Ventricular septal defect

Tablo 3. Comparison of results of screening with pulse-oximetry of studies from our country and all around the world

Study	Year	Infant count (n)	Sensitivity	Specificity	False positive rate
Thangaratinam et al[10]	2012	229.421	76.5%	99.9%	0.14%
deWahl Granelli et al[6]	2009	39.821	65.5%	99.8%	0.2%
Turska Kmieć et al[16]	2012	52.993	78.9%	99.9%	0.026%
Riede et al[23]	2010	41.442	77.8%	99·9%	0·1%
Dilli et al[18]	2019	4888	83.3%	99.9%	0.76%
Ozalkaya et al[17]	2016	8208	60%	99.8%	0.12%
Hamilçıkan and Can[19]	2017	4236	….	….	0.2%
This study	2020	2261	.....	99.3%	0.6%

Discussion

The cardiovascular malformation is responsible for 6.0-10.0 % of all infant deaths. Among congenital malformations, it constitutes 20.0-40.0 % of deaths (13). With the diagnosis and treatment possibilities developed in recent years, the importance of catching ductus-dependent critical congenital heart defects in the critical period has increased. Preoperative mortality and morbidity directly affect surgical success and long-term good results. For this reason, early diagnosis and treatment of children with congenital heart defects are recommended byscreening newborn infants with pulse-oximetry, which is a non-invasive and cheap method, for the early detection of critical congenital heart defects (7,14).

An increasing number of centers worldwide are reported to be using this method of screening (15). Thangaratinam et al. reported a specificity of 99.9% and a false positive rate of 0.05% in their meta-analysis (10). De-Wahl Granelliand colleagues. according to the screening results of 39.821 infants, reported a specificity of 62.0% reported and a sensitivity of 99.8% (6). Turska Kmiec and colleagues. reported high sensitivity and specificity with 78.9% and 99.9 % in their studies involving 51.698 infants (16).

Although it has not been introduced by the Ministry of Health as a mandatory screening program in our country, many centers from our country continue to share their screening results. Ozalkaya et al. reported the sensitivity and specificity of pulse oximetry screening in the diagnosis of critical congenital heart defects as 60.0 % and 99.9%, respectively (17). In a prospective study by Dilli et al. in which they shared data from centers of 4 different levels in our country, they determined a sensitivity of 83.3%, a specificity of 99.9%, a positive predictive value of 11.9%, and a negative predictive value of 99.9% (18). Among the studies, their study was the first feasibility study conducted before the decision of introducing a screening program by the ministry. Not surprisingly, the mean pre- and post-ductal saturation of the center of the highest level was the lowest. Sensitivity could not be determined in our study, as we could not diagnose any patient with critical congenital heart defects in our study. However, our specificity was as high as 99.3%, similarly to the literature.

In another study from our country, when pre- and post-ductal saturations of infants screened for critical congenital heart defects before and after postnatal 24 hours were compared, HamilÇıkan et al. revealed that infants screened earlier had a lower mean saturation (19). The false-positive rate was lower in the group screened earlier but the authors indicated that, in this group, cases including early neonatal sepsis and transient tachypnea of the newborn were determined in false-positive cases. Many studies are demonstrating that screening after the 24th hour in absence of evidence of congenital heart disease (cyanosis, tachypnea, etc.) significantly reduces false positivity without altering the sensitivity (10, 20, 21). However, if an earlier discharge is needed due to conditions of the hospital, saturation measurement in asymptomatic neonates should be delayed as much as possible (close to the 24th hour) and during discharge. The recommendation of the American Academy of Pediatrics is that the screening should be started after the 24th hour, if possible, and completed within second day of life (8). In our study, the mean screening time was over 24th hour; however, among our cases screened within the first 24 hours due to early discharge following a spontaneous vaginal birth, only one case had a false-positive result. In our study, among infants with a false-positive test result, we did not diagnose any case with an extra-cardiac cause including transient tachypnea of the newborn or sepsis. We attribute this situation to the fact that we follow the infants with respiratory distress, even mild, and suspicious general conditions under a

radiant warmer, and then give the infants to their mothers after we are certain about their conditions. Additionally, infants with their mothers are routinelybeing examined twice within 24 hours. In a recent study, Diller et al. reported that modifying the screening algorithm to repeat the pulse-oximetry test for once instead of twice might detect additional infants with a significant disease without a substantial increase in false-positive rate (22).

In studies in which screening for critical congenital heart defects with pulse-oximetry was performed, the false-positive rate varies between 0.1 % to 0.89 % (2). This rate was found to be 0.84 % by Ewer et al., 0.17 % by Granelli et al., and 0.10 % by Reide et al. (13, 23, 24). We attribute a higher false-positive rate in our study to our lower number of cases.

In this study, we could not detect any patient with critical congenital heart defects by screening. We attribute this result to the fact that almost all pregnant women who gave birth in our hospital, a center of perinatology, were followed by perinatologists who are working in cooperation with a pediatric cardiologist with experience in fetal echocardiography. In a study by Banait et al., they indicated that this screening did not statistically significantly contribute to the rate of diagnosis determined by prenatal ultrasonography and postnatal physical examination in centers with a high rate of diagnosis with critical congenital heart defects but this could not be applied to centers lacking these facilities (25).

The limitations of the study are that the study was retrospective and that we could not detect critical congenital cardiac patients in screening.

Similar to the world literature, screening results from our country reveals that this noninvasive, cost-effective, and easy-to-apply test has the quality to be applied to prevent overlooking of cases with critical congenital heart defects (Table-3). Based upon our study, we highlight that screening with pulse oximetry should be popularized particularly in peripheral regions providing secondary health care services, in addition to centers in which the patients are followed-up by a perinatologist and fetal echocardiography is available. Thus, overlooking of such patients in these centers seems more likely. Based on this study, we think that screening of critical congenital heart defects with pulse-oximetry should be included in the national screening program in our country.

Informed Consent: Written consent was obtained from the participants.

Conflict of Interest: Authors declared no conflict of interest.

Financial Disclosure: Authors declared no financial support.

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